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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,938	07/10/2001	Michael Econs	053884-5001	9281

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	**PAPER NUMBER**
1647	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/901,938	Applicant(s) ECONS et al.
	Examiner Christine Saoud	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-83* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 22-24, 32-33, 36-38, 43, 80, 82 and 83, drawn to nucleic acids, classified in at least class 435, subclass 69.1, for example.

II. Claim 17, drawn to a trangenic animal, classified in class 800, subclass 2.

III. Claims 18-19, 25-27, 34, 39-41, drawn to polypeptides, classified in at least class 530, subclass 300.

IV. Claims 20-21, 35, and 81 (in so far as it encompasses an antibody), drawn to antibodies, classified in class 530, subclass 387.1, for example.

V. Claims 28-31 and 42, drawn to inhibitors, classified in class undetermined, subclass undetermined (depends on the structure of the inhibitor).

VI. Claims 44-49, drawn to methods of diagnosing a disorder using a nucleic acid, classified in class 435, subclass 6, for example.

VII. Claims 50-53, drawn to a method of diagnosing a disorder using an antibody to a mutant, classified in class 436, subclass 501, for example.

VIII. Claims 54-59, drawn to a method of diagnosing using an antibody to FGF-23, classified in class 436, subclass 501, for example.

IX. Claim 60, drawn to a method of diagnosing tumor induced osteomalacia by detecting FGF23 expression, classified in class 435, subclass 6, for example.

X. Claims 61-63, drawn to a method of treatment by administration of an inhibitor, classified in class undetermined, subclass undetermined (depends on the structure of the inhibitor).

XI. Claims 64-66, 79, drawn to a method of treatment by administration of nucleic acid, classified in class 514, subclass 44, for example.

XII. Claims 67-69, 76-77 (in so far as they encompass administration of FGF-23 protein), drawn to a method of treatment by administration of FGF-23 polypeptide, classified in class 514, subclass 2, for example.

XIII. Claims 70-72, 76-77 (in so far as they encompass administration of an agent), drawn to a method of treatment by administration of an agent, classified in class undetermined, subclass undetermined (depends on the structure of the agent).

XIV. Claims 73-75, drawn to a method of treatment by administration of cells, classified in class 424, subclass 93.2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different method, such as in a method of detection of the polynucleotide in a sample, rather than in a method of making the polypeptide of Group III.

4. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group III could be used for an entirely different purpose such as in a method of treatment, rather than for the production of antibodies of Group IV.

5. Inventions I-V are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to chemically different compounds or products which can be made and used without each other. Furthermore, the inventions of Groups I-V lack a common utility which is based upon a common special technical feature which is disclosed as being responsible for the common utility.

6. Inventions I and (II, VI, IX, XI, XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different manner, such as in a method of making the polypeptide rather than in the methods of Groups (II, VI, IX, XI, XIV).

7. Inventions I and (VII, VIII, X, XII- XIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotide of Group I is not required for any of the methods or methods of making products of Groups (VII, VIII, X, XII- XIII).

8. Inventions II and (VI-XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the animal of Group II is not required for any of the methods of Groups (VI-XIV).

9. Inventions III and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II could be used in an entirely different manner, such as in a method of making antibodies rather than in the method of Group XII.

10. Inventions III and (VI-XI, XIII-XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptide of Group III is not required for any of the methods of Groups (VI-XI, XIII-XIV).

11. Inventions IV and (VII, VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group IV could be used in an entirely different manner, such as in a method of purifying the protein rather than in the methods of Groups VII. VIII.

12. Inventions IV and (VI, IX-XIV) are unrelated, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies of Group IV are not required for any of the methods of Groups (VI, IX-XIV).

13. Inventions V and (X, XIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inhibitors of Group V could be used in either the method of Group X or XIII.

14. Inventions VI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and/or goals.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Additional Restriction Requirements

In the event Group I or II or VI, IX or XI or XIV is elected:

16. The claims of Group I are not directed to a genus of compounds, but rather a multitude of distinct polynucleotides and variants having mutations from a distinct starting material. Each of the different polynucleotides and methods of use (Groups II, VI, IX, XI, XIV) are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of Group I (or any Group that utilizes the nucleic acids of Group I; i.e. Groups II, VI, IX, XI, XIV), Applicant is additionally required to elect a single polynucleotide for examination. For example, the nucleic acid encoding SEQ ID NO:2 versus encoding SEQ ID NO:2 with a mutation at position 176 versus encoding SEQ ID NO:2 with a mutation at position 179. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

In the event Group III or XII is elected:

17. The claims of Group III are not directed to a genus of compounds, but rather a multitude of distinct polypeptides and variants having mutations from a distinct starting material. Each of the different polypeptides and methods of use (Group XII) are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of Group III (or any Group that utilizes the polypeptides of Group III; i.e. Group XII), Applicant is additionally required to elect a single polypeptide for examination. For example, the polypeptide of SEQ ID NO:2 versus SEQ ID NO:2 with a mutation at position 176 versus SEQ ID NO:2 with a mutation at position 179. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

In the event Group IV or VII or VIII is elected:

18. The claims of Group IV are not directed to a genus of compounds, but rather a multitude of distinct antibodies which bind distinct polypeptides with distinct structures resulting in distinct properties (such as ability to identify mutations in a protein). Each of the different antibodies and methods of use (Groups VII or VIII) are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of Group IV (or any Group that utilizes the antibodies of Group IV; i.e. Groups VII or VIII), Applicant is additionally required to elect a single antibody for examination.

In the event Group V or X or XIII is elected:

19. The claims of Group V are not directed to a genus of compounds, but rather a multitude of distinct compounds with distinct activities selected from the group consisting of (1) reducing mRNA levels, (2) reducing polypeptide levels, and (3) reducing biological activity. The compounds are selected from the group consisting of antisense, ribozyme, antibody and peptidomimetic. Each of the different classes of compounds are independent and distinct because no common structural properties resulting in a common functional property are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of Group V (or any Group that utilizes the inhibitors of Group V; i.e. Groups X or XIII), Applicant is additionally required to elect a single inhibitor for examination.

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 7AM to 2PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud